PROPOSED CHANGES TO THE QUALITY SYSTEMS STANDARD

1. NEW AND RECONDITIONED INSTRUMENTS: change to 5.10.2.1.e [ISO draft 5.5.4.2.2.e], 5.8.c [ISO draft 5.5.5.7] and Appendix C section C.1 (#1)

Present Text

5.10.2.1 Demonstration of Capability

e) A demonstration of capability must be completed each time there is a change in instrument type, personnel, or test method.

5.8 EQUIPMENT AND REFERENCE MATERIALS

c) Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous calibrations or tests.

The following is the equivalent text in the ISO 17025 draft:

5.5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 5.4.9). **(17025: 5.5.7)**

Appendix C - DEMONSTRATION OF CAPABILITY

C.1 PROCEDURE FOR DEMONSTRATION OF CAPABILITY

A demonstration of capability (DOC) must be made prior to using any test method, and at any time there is a change in instrument type, personnel or test method (see 5.10.2.1).

Proposed Text:

5.10.2.1 Demonstration of Capability

e) A demonstration of capability must be completed each time there is a change in instrument type, personnel, or test method. *A DOC and Instrument Detection Limit must be completed for a newly acquired instrument or an instrument that has had its detection system replaced, modified, or refurbished. An instrument DOC does not need to include sample extraction, digestion or clean up. An instrument DOC includes a valid calibration curve and sensitivity check to establish instrument performance. An instrument DOC for a specific instrument does not need to be completed by each analyst using the instrument.*

5.8 EQUIPMENT AND REFERENCE MATERIALS

c) Any item of the equipment which has been subjected to overloading or mishandling, or which gives suspect results, or has been shown by verification or otherwise to be defective, shall be taken out of service, clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification or test to perform satisfactorily. *A determinative instrument (e.g. GC, GC/MS, ICP, AAS, VIS. SECTROPHOTOMETER etc.) must have a Demonstration of Capability, see **5.10.2.1 e**, before it is returned to service. An instrument Demonstration of Capability does not need to include sample extraction, digestion or clean up. An instrument DOC for a specific instrument does not need to be completed by each analyst using the instrument*. The laboratory shall examine the effect of this defect on previous calibrations or tests.

The following is the equivalent text in the ISO 17025 draft:

5.5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service. It shall be isolated to prevent its use or clearly labeled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly. *A determinative instrument (e.g. GC, GC/MS, ICP, AAS, VIS. SECTROPHOTOMETER etc.) must have a Demonstration of Capability, see **5.10.2.1 e**, before it is returned to service. An instrument Demonstration of Capability does not need to include sample extraction, digestion or clean up. An instrument DOC for a specific instrument does not need to be completed by each analyst using the instrument*. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure (see 5.4.9). **(17025: 5.5.7)**

Appendix C - DEMONSTRATION OF CAPABILITY

C.1 PROCEDURE FOR DEMONSTRATION OF CAPABILITY

A demonstration of capability (DOC) must be made prior to using any test method, and at any time there is a change in instrument type, personnel or test method (see 5.10.2.1). *A DOC and Instrument Detection Limit must be completed for a newly acquired instrument or an instrument that has had its detection system replaced, modified, or refurbished. An instrument DOC does not need to include sample extraction, digestion or clean up. An instrument DOC for a specific instrument does not need to be completed by each analyst using the instrument.*

Chapter 1 Appendix A, Glossary

Note: This is the addition of new term to be referred the Program Policy and Structure (Chapter 1) committee.:

Instrument Demonstration of Capability: *a procedure to establish the ability of an instrument to generate acceptable accuracy, precision, and sensitivity. An instrument DOC does not need to include sample extraction, digestion or clean up. An instrument DOC includes a valid calibration curve and sensitivity check to establish instrument performance. (NELAC)*

Note citation used above is ***5.10.2.1 e*** not ***5.10.2.1 d***

2. ONE STANDARD CALIBRATION: change to 5.9.4.2.1.f [ISO draft 5.5.5.2.2.1.f] (#4)

Current Standard:

f) Results of samples not bracketed by initial instrument calibration standards (within calibration range) must be reported as having less certainty, e.g., defined qualifiers or flags or explained in the case narrative. The lowest calibration standard must be above the detection limit.

DRAFT Suggested Change:

f) Results of samples not bracketed by initial instrument calibration standards (within calibration range) must

be reported as having less certainty, e.g., defined qualifiers or flags or explained in the case narrative. The lowest calibration standard must be above the detection limit. *Special Guidance for ICP technology: The ICP is calibrated and the linearity is established as required by the method and/or manufacturer. This may include the establishment of the curve using a zero point and a single standard followed by analyses of reference standards that establish the linear range. The minimum quantitation limit (reporting limit) should be defined and demonstrated by the successful analysis of a reference standard at the designated MQL concentration. The linear range shall be routinely checked at a frequency and procedure as established by the method or manufacturer. If an individual sample analysis produces results above the single point calibration standard, one of the following actions must occur: (1) Analyze a reference standard at or above the sample value that validates the linearity; (2) Dilute the sample such that the result falls below the single point calibration curve; (3) Report the data with an appropriate data qualifier and/or explain in the case narrative.*

3. MEDIA PREPARATION: change to Appendix D.3.6.a (#7)

Current Standard:

D.3.6.

a) Culture media may be prepared from commercial dehydrated powders or may be purchased ready-to-use. Preparation from different chemical ingredients shall not be done unless the media is not available commercially or unless specified by the method.

DRAFT Suggested Change:

D.3.6.

a) Culture media may be prepared from commercial dehydrated powders or may be purchased ready-to-use. Media prepared from basic ingredients must be tested for performance (e.g. by the use test), prior to first use, to demonstrate that it is of equivalent or better quality than commercially available media.

4. TESTING FOR RESIDUAL CHLORINE IN MICROBIOLOGY SAMPLES: (#12)

No text to present at interim but will be a discussion item discussion of possible change to Appendix D.3

~~5. ASBESTOS:~~

~~(New Appendix: D.6 ASBESTOS TESTING)~~